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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,218	07/23/2001	Yongxing Qiu	CL/V-31563P1	4902
1095	7590	05/19/2004	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 430/2 EAST HANOVER, NJ 07936-1080			MICHERNER, JENNIFER KOLB	
			ART UNIT	PAPER NUMBER
			1762	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No. 09/911,218	Applicant(s) QIU ET AL.	
	Examiner Jennifer K. Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-17 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/14/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. In the previous office action, Examiner stated: "To obviate the new matter objection, Applicant removed formulas (5), (6), and (5a) from the specification. In so doing, reference to characters named within those formulas remains in the specification. For example, the phrase "wherein L is C₂-C₆-alkyl" remains in the specification to define "L" of formula (5), even though L is no longer present in a formula. This is not clear." In Applicant's response, Applicant made amendments to the specification, however, these amendments were made in a previous amendment and did not remedy the objection reiterated above.

Examiner maintains this objection.

In addition to the example above where the term "L" is defined even though "L" is no longer present, there are other similar references to formulas which no longer exist. Examiner kindly suggests Applicant carefully review the specification for such instances.

Appropriate correction is required.

Information Disclosure Statement

2. The documents cited, but not considered, in the information disclosure statement filed 4/14/2003 have been considered in the newly submitted IDS of 11/14/03, along with the additional U.S. reference.

Examiner's Suggestions

3. In claims 4 and 5, for clarity, Examiner suggests the use of commas after the words "wherein" and "depositing".

Examiner maintains the above suggestion.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 4-13, and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Examiner maintains the rejection.

The rejection of claims 2-3 has been withdrawn based on Applicant's cancellation of these claims.

As necessitated by amendment, the following new new matter rejection is made:

6. Claims 1, 4-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrase "provided each of the polymer and hydrophilic polymer is different from any one of the first polyionic material and the second polyionic material" appears to be new matter. Examiner cannot find basis for this newly-added limitation in the originally-filed disclosure. While the specification gives some examples of polymers in the final layer that are indeed different from the examples of the polyionic materials, there is no basis for claiming that the two *must* be different. In fact several of the polyionic materials may be bioactive in nature, just as the polymers may be.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-2, 5-6, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (U.S. Pat. 5,409,731).

Examiner maintains the rejection of claims 1, 5-6, and 12-13.

The rejection of claim 2 has been withdrawn due to Applicant's cancellation of the claim.

9. The rejection of claims 1, 3-9, 12, 13, and 17 under 35 U.S.C. 102(b) as being anticipated by Sheu et al. (5,807,636) has been withdrawn, as necessitated by Applicant's amendment, in favor of the newly-applied rejection below.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. The rejection of claims 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Sheu has been withdrawn, as necessitated by Applicant's amendment and in favor of the newly-applied rejection, below.

As necessitated by Applicant's amendment, the following new rejection, modified from the previous office action, is applied:

12. Claims 1, 4-13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheu (5,807,636) in view of Wang et al. (6,011,082).

As outlined in the previous office action, Sheu et al. teaches a method of modifying the surface of an article to improve wettability comprising depositing a polyelectrolytic layer on the surface of the article, ionically bound thereto (abstract; col. 1, line 11; col. 2, lines 18 and 65; throughout). The ionic bonds meet Applicant's limitation of "not covalent". One or more additional polyelectrolytic layers may be coated thereon, with alternating charges (col. 7, line 32 and line 37). The charges along the polymer backbone of the polyelectrolytic layer form "reactive sites" as required by Applicant and any of the combination of layers acts as Applicant's polyelectrolytic tie layer.

Regarding the newly-added limitation in claim 1, Sheu fails to teach that the final layer or "active" layer is applied covalently and is different from the first polyionic materials applied above. In the previous office action, Examiner argued that the final layer of Sheu acts as the "active agent" of claim 1 and that the limitations of claim 3 (now included in claim 1), which further required the active agent to be a polymer, was met by the final polymer layer of Sheu (col. 7, lines 33). So, while Sheu teaches a final layer that is "active" and a "polymer", Sheu fails to teach that this layer is applied covalently or is different than any other layer.

As cited in the previous office action, Wang et al. (6,011,082) teaches surface modification of contact lenses with polyionic chemicals attached to the substrate non-covalently for subsequent attachment of active agents, such as heparin (see Figure 2; abstract; col. 2, lines 26-36). The heparin is said to "bond" to the "reactive functional groups" of the polyionic materials, such as amino groups (col. 10, line 17 and lines 25-30; Figs. 1-2), indicating a reactive, i.e., covalent bond. Heparin is a polymer that is different from any of the previously applied chemicals of Sheu or Wang and serves to provide a surface which enhances biocompatibility by decreasing clotting on the lens surface.

Since Sheu teaches a polyionic tie layer for contact lenses and Wang teaches attachment of an active agent to a non-covalently attached ionic layer on a contact lens to improve biocompatibility, Wang would have reasonably suggested the use of heparin in the method of Sheu. It would have been obvious to one of ordinary skill in the art to use the teachings of Wang in the method of Sheu to provide Sheu's contact lenses with

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enhanced compatability with the human eye during contact lens wear by adding a heparin layer thereto.

In regard to claims 4 and 5, Sheu teaches, as outlined above, the deposition of a polyelectrolyte layer, followed by one or more additional polyelectrolyte layers, as outlined in the previous office action.

As outlined in the previous office action, as required by claim 6, solutions are used for deposition in Sheu (col. 7, line 50). Regarding claim 7, Sheu teaches dipping for use in applying the successive layers with opposite charges (col. 7, line 31). Alternatively, a single solution can be used by Sheu for the polyelectrolyte layers (col. 7, line 45), as required by claim 8. Other methods of application taught by Sheu include spraying, as required by claim 9.

Regarding claims 12 and 13, Sheu teaches the use of such modification on a contact lens (examples), a biomedical device.

Regarding claim 17, as outlined in the previous office action, Sheu specifically teaches that the first tie layer may be applied by spraying the polyelectrolyte layer (col. 7, line 21), followed by dip coating a second polyelectrolyte layer of opposite charges (col. 7, line 31 and line 38).

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As outlined in the previous office action and above, Sheu teaches the use of dipping or spraying the first polyelectrolyte layer and dipping the second. Sheu fails to specifically teach that the subsequent layer may also be formed by spraying, as required by claim 10.

Since Sheu teaches the interchangeability of dipping and spraying for applying the first layer, it would have been obvious to one of ordinary skill in the art, using the teachings of Sheu, that the second layer could be sprayed, rather than dipped, with the expectation of similar, successful results since Sheu teaches the appropriateness of spraying versus dipping when applying charged polyelectrolyte coatings.

Claim 11 then requires that the coatings be applied together, instead of successively, by spraying. As outlined above, Sheu envisions the use of one coating solution containing more than one polyelectrolyte coating for the dipping operation. For those reasons outlined immediately above, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to apply the polyelectrolyte materials together in one spraying operation, just as was taught in the dipping operation with the expectation of similar results because dipping and spraying are taught to be interchangeable for coating polyelectrolytes.

Response to Arguments

13. Applicant's arguments filed 3/1/2004 have been fully considered but they are not persuasive.

Applicant continues to argue that the phrase "not covalently" is not new matter and cites the phrases "adsorbed onto and/or heteropolarly bound" and "entrap" to support his argument.

There remains no basis for the broad limitation "not covalently attached" in claim 1, as outlined in several of the previous office actions. The phrase "not covalently" encompasses a broader range of potential interactions than is disclosed by the originally-filed disclosure. "Not covalently" is inclusive of ionic, van der Waals, hydrogen bonding and various other types of attachment mechanisms not envisioned by the originally-filed disclosure. Examiner suggests Applicant claim the specific attachment mechanisms which are outlined by the specification as an active method step instead of using the broad negative limitation of "not covalently" to describe the attachment.

Applicant argues that Nakagawa fails to teach the newly-added claim limitation of the amendment, namely covalent attachment of an active agent to the reactive sites, such that the active agent is an antimicrobial, polymeric initiator, polymer, or hydrophilic polymer, wherein the two latter polymers should be different from any one of the first or second polyionic materials.

Examiner disagrees.

Nakagawa teaches the use of polymeric poly-functional compounds capable of "reacting with" the reactive groups of the previously applied agent (col. 4, line 55-col. 5, line 23). The reaction between the reactive groups is covalent and the polyfunctional compound is not the same as the amino-group-containing polymer.

Applicant argues that Sheu fails to teach the limitation of the most recent amendment. The Sheu rejection has been modified, above, in view of the Wang reference to teach the newly-added limitation. Applicant's arguments regarding Sheu have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

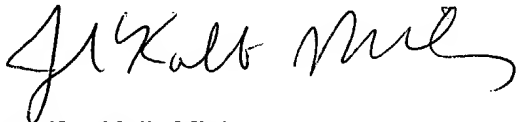
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 571-

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272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415.

A handwritten signature in cursive script, appearing to read "J Kolb Michener".

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
May 14, 2004